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10/590,311	08/23/2006	Francisco Javier Vila Pahi	Q108-487	8146
23373 7590 03/05/2010 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037				
EXAMINER KRISHNAN, GANAPATHY				
ART UNIT		PAPER NUMBER		
1623				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/590,311

Applicant(s)

VILA PAHI ET AL.

Examiner

Ganapathy Krishnan

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date: _____

DETAILED ACTION

The amendment filed 10/23/2009 has been received, entered and carefully considered.

The following information has been made of record in the instant amendment:

1. Claims 1-27 have been canceled.
2. New Claims 28-38 have been added.
3. Remarks drawn to rejections under 35 USC 112-first and second paragraphs and 103.

The following have been overcome:

4. The rejection of Claims 26-27 under 35 U.S.C. 112, first paragraph for lack of enablement has been rendered moot by cancellation of claim 26-27.

5. The rejection of Claim 23 under 35 U.S.C. 112, second paragraph, as being indefinite for recitation of the terms, "whose structure is derived from a sulfated polysaccharide" followed by Markush members, has been rendered moot by cancellation of claim 23.

Claims 28-38 are pending in the case.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

New Claims 28-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cullis-Hill et al (US 5,145,841, of record) in view of Dictionary.com (2002, page 3, of record) and Martindale: The Extra Pharmacopoeia 1996, page 11 (of record).

Hill et al, drawn to antiinflammatory compounds, teach that polysulfated polysaccharides like alginic acid, pectin and inulin have a variety of biological activities including antiinflammatory activity (col. 5, lines 53-64) and are useful for treatment of osteoarthritis (col. 7, lines 39-40; col. 8, lines 46-59; col. 12, lines 8-26; col. 24, lines 37-39). According to Hill the sodium salt of polysulfated xyloside is an inhibitor of PMN elastase and other enzymes that degrade connective tissue and articular cartilage. The polysulfated xyloside binds to articular cartilage and connective tissues (col. 6, lines 32-46) and promotes joint hyaluronate and articular cartilage which provide the rheological properties (col. 7, lines 14-24). The said sulfated polysaccharides can also be used as their salts (col. 9, lines 55-58). Even though there is no

specific reference to the use of sodium salt of inulin sulfate at col. 9, lines 55-38, Hill teaches sodium salt of the polysulfated polysaccharides abbreviated as SP 54 and Arteparon that are inhibitors of cartilage degrading enzymes having a sulfur content (i.e., degree of sulfation) of about 16% and 13% respectively (col. 6, lines 8-11 and 57-61) and also discloses that selectivity of biological activity of the polysulfated polysaccharides is desirable and has been achieved by varying the degree of sulfate substitution (col. 7, lines 51-54). Since the sodium salt of SP54, a structurally close polysulfated polysaccharide is an inhibitor of connective tissue and articular cartilage degrading enzyme, one of ordinary skill in the art will also substitute sodium ion in the inulin polysulfate taught by Hill instead of the other trivalent metal ions. Even though the degree of sulfation taught by Hill is lower than that claimed in instant claims 9-10 and his reference to degree of sulfation may be in the context of anticoagulant activity, it is a suggestion to one of ordinary skill in the art to adjust the degree of sulfation (as one of the variables) in order to achieve optimal beneficial effects.

According to definitions in Dictionary.com both rheumatoid and osteoarthritis are known to involve degradation of bone joints.

According to Martindale both osteoarthritis and rheumatoid arthritis are characterized by degradation/destruction of cartilage. According to Hill polysulfated xyloside binds to articular cartilage and connective tissues (col. 6, lines 32-46) and promotes joint hyaluronate and articular cartilage which provide the rheological properties.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the polysulfated inulin as instantly claimed in a method of treating osteoarthritis since the use of the sulfated polysaccharides as instantly claimed is seen to be suggested for the

treatment of the related rheumatoid arthritis. Both osteoarthritis and rheumatoid arthritis are characterized by degradation/destruction of cartilage.

One of skill in the art would be motivated to use the active agents in the method of treatment as instantly claimed since they inhibit the release and action of the serine proteinases. The proteoglycans, which confer the property of resilience of the joints, are depleted due to excessive degradation of proteinases. Hence inhibition of the degradation of the proteinases inhibits the depletion of the proteoglycans, which are needed to maintain the resilience of joints. One of skill in the art would expect structurally related polysulfate polysaccharides to perform the same functions and would look for other related sulfated polysulfated polysaccharides and oligosaccharides for use in the method of treatments as instantly claimed. One of ordinary skill in the art would also expect the polysulfated oligosaccharide of inulin to exhibit anti-rheumatoid and anti-osteoarthritic activity and would substituted them for the polysulfated inulin I the instant method of treatment. Reasonable expectation of success for such a substitution is seen in the prior art.

Response to Applicants Arguments

Applicants have traversed the rejection under 35 USC 103 of record with respect to the new claims 28-38 arguing that:

1. Treatments for osteoarthritis and rheumatoid arthritis are different. In this regard applicants list different types of drugs and arguing that some of them are used only for treating osteoarthritis and not for rheumatoid arthritis and vice versa. On this basis the treatment of osteoarthritis and rheumatoid arthritis are clearly delineated in the art. Treatment of rheumatoid

arthritis is directed towards inflammation and treatment of osteoarthritis is directed towards slowing the progression of articular cartilage loss and marginal central new bone formation.

2. Hill teaches away from using inulin sulfate because such compounds would not have utility found by the present inventors (Hill; col. 10, lines 38-53). Hill teaches complexes formed between polysulfated polysaccharides and metal ions and not salts of these and does not teach oral administration.

3. Although sodium salts of some sulfated polysaccharides are known for the treatment of osteoarthritis the present inventors have surprisingly found that orally administered inulin polysulfate sodium salt has unexpectedly superior effectiveness compared to orally administered chondroitin sulfate at the same dose (ref: Rule 132 Declaration filed Jan. 27, 2009). This means that not all polysulfated polysaccharides would have the same effectiveness.

3. Komai is drawn to the use of gellan sulfate.

Applicants' arguments and the attached references and the Declaration filed earlier have been considered but are not found to be persuasive.

Just listing different types of drugs and arguing that some of them are used only for treating osteoarthritis and not for rheumatoid arthritis and vice versa is not seen as evidence that the treatments of osteoarthritis and rheumatoid arthritis are different. The drugs cited by the applicants are different from the one instantly claimed and doesn't mean that inulin polysulfate also can be used only for either one of the conditions. According to definitions in Dictionary.com both rheumatoid and osteoarthritis involve degradation of bone joints. According to Martindale both osteoarthritis and rheumatoid arthritis are characterized by degradation/destruction of

cartilage. Since both have characteristics in common one of ordinary skill in the art would use inulin polysulfate for the treatment of both types of arthritis.

Hill teaches that the compounds of his invention including inulin polysulfate are useful for the treatment of rheumatoid arthritis and osteoarthritis (col. 12, lines 8-10). At col. 10, lines 50-53, Hill teaches that the prior art, Lucas et al that he mentions in the previous paragraph does not disclose the compounds of his invention nor the utility found by Hill. Applicants' interpretation regarding the teaching of Hill at col. 10, lines 38-53 is not correct.

Applicants finding that that orally administered inulin polysulfate sodium salt has unexpectedly superior effectiveness compared to orally administered chondroitin sulfate at the same dose (ref: Rule 132 Declaration filed Jan. 27, 2009) is not unexpected. According to applicants sodium salts of some sulfated polysaccharides are known for the treatment of osteoarthritis. One of ordinary skill in the art would always look for other more effective polysulfated polysaccharides. This is routine in the art. Since inulin sulfate is suggested by Hill for the treatment of osteoarthritis and rheumatoid arthritis one of ordinary skill in the art would want to substitute sulfated polysaccharides like chondroitin sulfate with inulin sulfate in order to see if it is superior to chondroitin sulfate. Just finding an agent that has better activity compared to another agent for the same method of treatment is not seen as an unexpected result. It is routine in the art to do that. Moreover, one of ordinary skill in the art would not expect the activity of different polysulfated polysaccharides to be the same.

The Komai reference is not used in the rejection above since the instant new claims are drawn to the use of only inulin sulfate. Komai teaches the use of gellan sulfate for treating

rheumatoid arthritis. Gellan sulfate was one of the active agents claimed in the claims presented previously.

The instant invention is seen to be rendered obvious by the prior art.

Conclusion

Claims 28-38 are rejected

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ganapathy Krishnan/
Examiner, Art Unit 1623

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623